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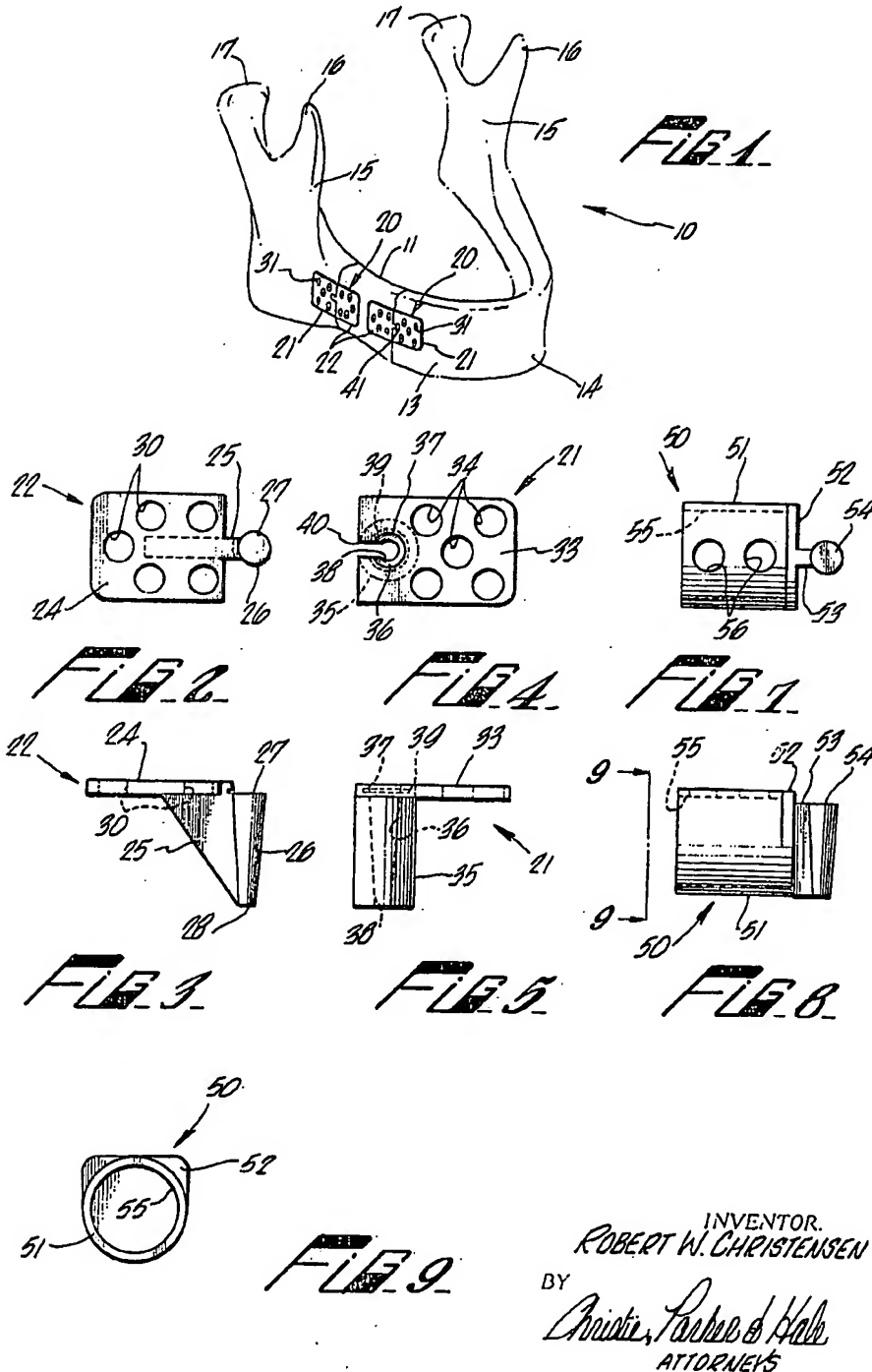
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ORTHOPEDIC PROSTHETIC APPLIANCES FOR ATTACHMENT TO BONE

Filed Sept. 27, 1967

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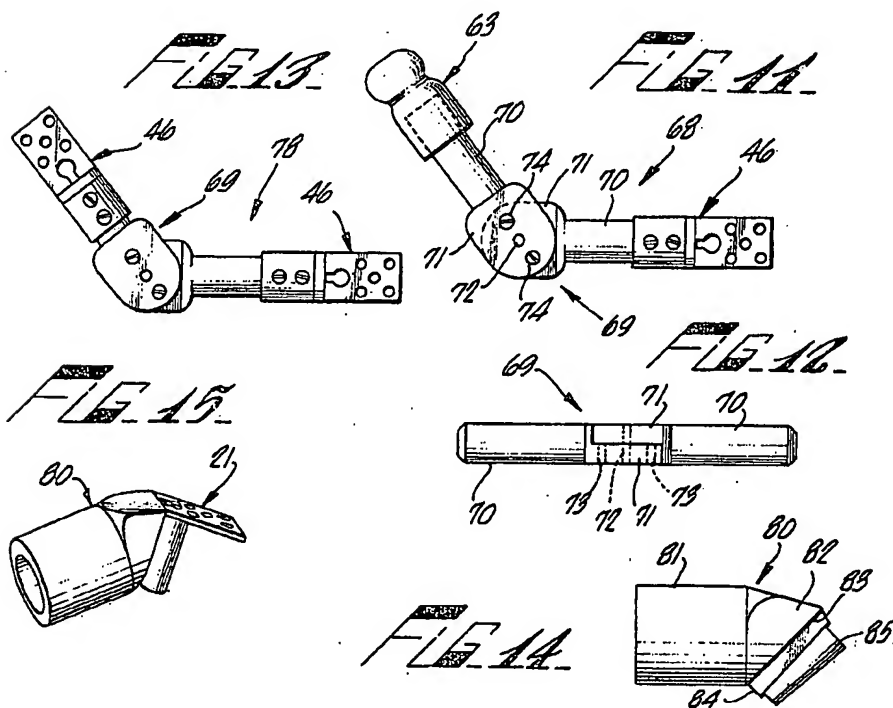
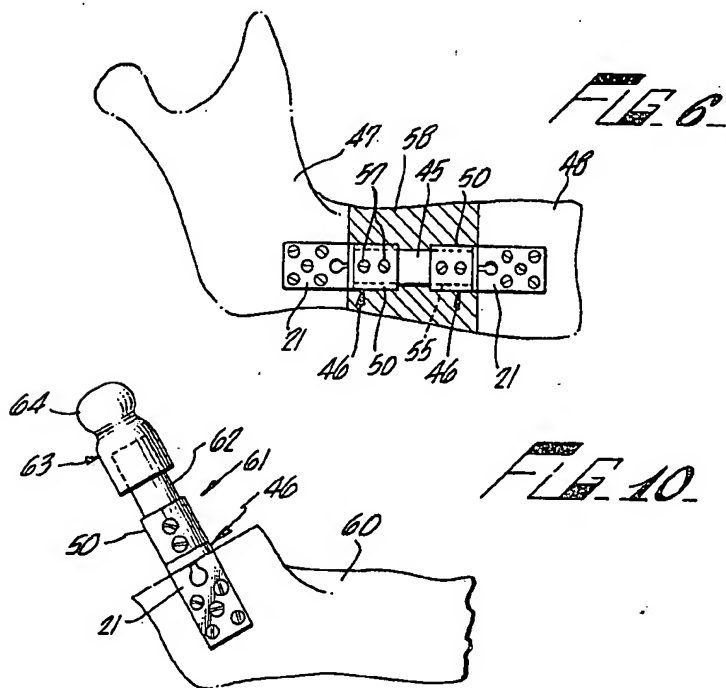
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**ORTHOPEDIC PROSTHETIC APPLIANCES FOR
ATTACHMENT TO BONE**
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U.S. Cl. 3—1 10 Claims

ABSTRACT OF THE DISCLOSURE

A coupling assembly for stabilization of bone grafts, and for mounting of artificial members to replace surgically removed bone sections. A female coupler has a plate for mounting on an anchor bone in the patient's body, and a post extends from the plate into a hole drilled in the bone. The post has a conical socket, and a male coupler includes a conical lock pin shaped to fit snugly in the socket. The male coupler is secured by a plate to a grafted bone, or alternatively is secured to a strut member which replaces a removed bone section. In one form, the strut member includes a hinged or pivoted portion so the strut can be angulated during surgical installation and locked at a desired angulation.

BACKGROUND OF THE INVENTION

This invention relates to a prosthetic appliance useful to anchor bone grafts in place, and also useful to replace sections of diseased or injured bone. The appliance has particular utility with respect to surgery involving the human mandible or lower jawbone, and the invention will be described in the context of this application.

It is sometimes necessary for a surgeon to remove a portion of the mandible, or perhaps the entire mandible, due to the development of cancer or other disease, or to a blow resulting in serious fracture or shattering of this bone. Whenever possible, it is important to replace the surgically removed portions with a bone graft taken from another part of the patient's body, or with an artificial member which will at least partially duplicate the skeletal structural support afforded by the natural bone. Such treatment aids the patient in maintaining an ability to chew food, and also helps to preserve a natural facial appearance as the mandible largely determines the contour of the lower face and chin.

In the past, surgeons have been limited in their ability to complete a structurally sound bone graft by the lack of suitable fastening devices to secure the graft in place. There has been a particular need for appliances which would permit temporary installation of a graft or artificial member to check for proper fit and contour before permanent placement. Similarly, there exists a need for artificial members which can be dimensioned and contoured during surgery to obtain the best possible correspondence to a removed bone.

I have developed a set of modular appliances which meet these needs, and which are adjustable to an optimum configuration during surgery. Initial dimensional estimates made from pre-surgery X-rays can be refined or corrected while surgery is in progress. The appliances permit trial installation of a graft or artificial member to check for a desired fit and contour, and also are adapted to rigidly secure the graft or member in place when a desired configuration has been achieved.

SUMMARY OF THE INVENTION

Briefly stated, the invention includes a coupling assembly for securing a member (such as a bone graft or an artificial member) to a bone, the bone having a lateral hole drilled therein adjacent one of its ends. The assembly

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comprises a female coupler having an anchor plate with a hole therethrough to accept a bone screw for securing the plate to the bone. An elongated post is secured at one end of the plate to extend perpendicularly therefrom to fit in the lateral hole when the plate is secured to the bone. The post further defines a lock socket extending longitudinally therein. A male coupler has a body portion adapted to be secured to the bone graft or artificial member, and an elongated lock pin is secured to the body portion and shaped to make a snug fit in the lock socket of the female coupler.

Preferably, the lock socket is tapered and the pin on the male coupler is conically shaped to fit snugly in the lock socket. The lock pin is preferably somewhat shorter than the socket so the head of the pin is disposed within the socket and spaced from the entrance end of the socket when the pin is fitted in the female coupler. An annular groove in the entrance end of the lock socket provides an anchor for a retaining means such as a metal fastener of a viscous hard-setting material such as cement or plastic.

In one form, the male coupler has a body portion with a strut member extending therefrom. The strut is an artificial member which replaces a bone or portion of bone removed during surgery. The strut member can include a hinge or pivoted element so the strut can be angulated to simulate the contour of the bone being replaced.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described in detail with reference to the attached drawings, in which:

FIG. 1 is a perspective of a mandible from which a bone section has been removed and replaced by a bone graft secured in place by coupling assemblies according to the invention;

FIG. 2 is a plan view of a male coupler according to the invention;

FIG. 3 is an elevation of the male coupler;

FIG. 4 is a plan view of a female coupler;

FIG. 5 is an elevation of the female coupler;

FIG. 6 is an elevation of a mandible from which a section has been removed and replaced by a prosthetic appliance according to the invention;

FIG. 7 is a plan view of a male coupler having a socket to accept a strut member;

FIG. 8 is an elevation of the male coupler shown in FIG. 7;

FIG. 9 is a view on line 9—9 of FIG. 8;

FIG. 10 is an elevation of a mandible from which the ramus and condyle portions have been removed and replaced by a coupler and strut member according to the invention;

FIG. 11 is an elevation of a pivoted prosthetic appliance for rebuilding a mandible from which the natural bone extending from chin to condyle has been removed;

FIG. 12 is a plan view of a portion of the pivoted appliance shown in FIG. 11;

FIG. 13 is an elevation of a prosthetic appliance useful in rebuilding a mandible from which a chin-to-ramus section has been removed;

FIG. 14 is an elevation of an angulated male coupler; and

FIG. 15 is a perspective view of the angulated male coupler engaged with a female coupler.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows human mandible or lower jawbone 10 in which a section of bone has been removed and replaced by a bone graft 11, the graft being secured in place by appliances according to the invention. The mandible is a

U-shaped bone having a generally horizontal body portion 13 with an anterior prominence 14 defining the chin in the facial skeletal structure. An ascending branch or ramus 15 extends upwardly from each end of the body portion.

The upper end of each ramus terminates in a coronoid process 16 and a condyloid process or condyle 17. The condyle is a knob-shaped prominence which fits in a cup-shaped socket known as the glenoid fossa formed in the temporal bone (not shown) of the skull. The condyle, glenoid fossa, and supporting muscle tissue define a temporomandibular joint which permits the lower jaw to be freely movable.

Bone graft 11 is secured in mandible 10 by a pair of coupling assemblies 20, each of which includes a female coupler 21 and a male coupler 22. Male coupler 22 (see FIGS. 2-3) includes an anchor plate 24 having a central flange 25 extending generally perpendicularly from its lower face at one end thereof. Secured to the flange and longitudinally spaced from the anchor plate is a conically tapered lock pin 26 having a longitudinal axis which is generally perpendicular to the major plane of the anchor plate.

The lock pin has a large end 27 adjacent the anchor plate and a small end 28 remote from the anchor plate. Large end 27 is preferably stepped downwardly from the top surface of the anchor plate as shown in FIG. 3. The end of the anchor plate remote from the lock pin includes a plurality of holes 30 therethrough to accept conventional bone screws 31 (see FIG. 1) used to secure the male coupler to a bone.

Female coupler 21 (see FIGS. 4-5) also includes a generally rectangular anchor plate 33 having a plurality of holes 34 formed through one end thereof to accept bone screws 31. An elongated cylindrical post 35 extends perpendicularly from the other end of the plate, and is preferably positioned on the longitudinal centerline and at the edge of the plate. A conical socket 36 is formed through the plate and post, and has an axis generally perpendicular to the anchor plate.

Socket 36 has a large end 37 at the top surface of the plate and a small end 38 at the end of the post remote from the plate. An annular groove 39 is formed in the anchor plate adjacent the large end of the socket and spaced slightly from the upper surface of the anchor plate. A continuous slot 40 extends from the end of plate 33 and through the sidewall of post 35 into communication with socket 36.

The male and female couplers are assembled by inserting the small end of lock pin 26 in the large end of socket 36, and then moving the couplers with respect to each other until the lock pin is fully seated in the socket. The pin and socket are dimensioned such that the upper surfaces of the coupler anchor plates will be level and even when the pin is snugly seated in the socket with large end 27 just below annular groove 39. When the couplers are so assembled, flange 25 fits snugly in slot 40, and the adjacent end faces of the two anchor plates abut each other.

Separation of the assembled couplers is thereafter prevented by inserting a fastening or retaining means in the open large end of the socket above the large end of the pin. For example, a quick-setting cement 41 (see FIG. 1) or plastic material can be flowed into the upper end of the socket and into the annular groove. When this material sets, it forms a seated barrier which prevents inadvertent retraction of the lock pin from the socket. Alternatively, a simple fastener such as a conventional metal or plastic C-ring (not shown) can be contracted to pass through the upper end of the socket and then expanded in the annular groove to be locked in place.

It is believed that the most satisfactory procedure for installing the female couplers in the bone-graft situation shown in FIG. 1 is to secure these couplers in place before the diseased section of bone being replaced by the

graft is removed. After the bone is exposed during surgery, the surgeon determines the section to be removed, and then drills lateral holes in the adjoining sections of retained bone to accept posts 35 of the female couplers. The posts are then inserted in the lateral holes, and the anchor plates of the female couplers are secured in place with conventional bone screws as shown in FIG. 1.

The diseased section of bone is then removed using a conventional bone saw, and the cut is made immediately adjacent the slotted end of the female coupler. Drilling the lateral holes and installing the female couplers prior to removal of the diseased bone section lessens the risk of injury or fragmentation of the bone portions to which these couplers are secured.

The combination of the bone screws and the post (fitted snugly in the lateral hole in the retained bone) provides a rigid and strong mounting for the female coupler. Furthermore, the female coupler serves as a guide for the bone saw as a cutting plane is defined by the edge of the plate and the periphery of the post, and the saw can follow and be guided by these members to insure cutting along a desired line. This guidance is of considerable assistance to the surgeon as his direct view of the bone may be partially or intermittently obscured by blood.

Bone graft 11 is then temporarily inserted in the gap left by the removed bone section to check for proper fit. If the fit is satisfactory, a pair of male couplers are then installed at opposite ends of the bone graft by securing the anchor plates of the couplers to the graft by bone screws as shown in FIG. 1. The graft is then again installed in the gap left by the removed bone section, with the male couplers being engaged with the respective female couplers previously installed. The couplers are then locked together with a restraining means such as cement or a C-ring as described above.

In some situations, it may not be possible to replace the removed section of bone with a bone graft, and in such cases a metal or plastic strut or other artificial member can be installed in place of the removed bone. This procedure is illustrated in FIG. 6 in which a cylindrical strut 45 is secured by a pair of coupling assemblies 46 between ramus 47 and body 48 portions of a mandible. Coupling assemblies 46 each include a female coupler 21 fabricated and installed as already described above. A pair of male couplers 50 of modified form are used in the coupling assemblies in order to accommodate and be secured to strut 45.

Male coupler 50 is shown in detail in FIGS. 7-9, and includes a hollow tubular body portion 51 with a wall 52 secured across and closing one end thereof. A flange 53 extends from wall 52, and a tapered lock pin 54 (identical to lock pin 26 described above) is secured to the flange. The lock pin is shorter than the outer diameter of the tubular body portion such that the large end of the lock pin is stepped downwardly from the top surface of the body portion just as in male coupler 22 described above. The hollow body portion of the male coupler defines a cylindrical strut socket 55, and a pair of holes 56 extend laterally through the sidewall of the body portion to accept screws 57 (see FIG. 6) for securing strut 45 in the strut socket.

Referring to FIG. 6, female couplers 21 are installed as already described, and the diseased section of bone is subsequently removed. Strut 45 is cut to length, and temporarily inserted in strut sockets 55 of the two male couplers which are then engaged with the female couplers. The fit of strut 45 is then checked, and adjustments in length can be made before the strut is secured in the male couplers.

When a satisfactory fit has been achieved, screws 57 are installed to secure the strut in the male couplers, and the male couplers are in turn inserted in the sockets of female couplers 21. The couplers are locked together with a fastening means such as cement or a C-ring fastener as described above.

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In some cases, it may be desirable to cover the exposed periphery of the strut and male couplers with a tubing or filling material 58 (shown in section in FIG. 6) such as silicone rubber (as sold under the trademark "Silastic") or a similar material which is compatible with the body. Alternatively, strut 45 may be larger in diameter than the one shown in FIG. 6, and the male couplers can be formed with correspondingly larger body portions and strut sockets to accommodate the larger strut.

In FIG. 10, the entire upper portion of the ramus of a mandible 60 has been removed and replaced by a prosthetic assembly 61 secured to the intact portion of the ramus. A coupling assembly 46 (as described above) is secured to the lower part of the ramus, and includes a female coupler 21 and a male coupler 50 having a strut socket in which a strut 62 is secured. An artificial condyle member 63 is fitted over the free or distal end of strut 62, and is secured in place by cement or screws (not shown). The upper end of condyle member 63 is formed as a knob-shaped prominence 64 which simulates the contour of natural condyle 17 as shown in FIG. 1. This prominence seats in the glenoid fossa of the temporal bone, and permits reconstruction of the temporomandibular joint to allow movement of the reconstructed mandible.

The appliances of this invention are also useful in cases where the entire ramus and a part of the body portion of the mandible must be removed. FIG. 11 shows an appliance 68 useful in this type of problem. The appliance includes a coupling assembly 46 and an artificial condyle member 63 as described above. A hinged strut assembly 69 is secured to and extends between the coupling assembly and the condyle member. Assembly 69 includes a pair of struts 70 each of which has an inwardly stepped flat flange 71 extending therefrom. As best seen in FIG. 12, the flanges are positioned in face-to-face relationship, and are pivotally secured together by a pin 72 inserted therethrough. A pair of clearance holes 73 are predrilled through one of the flanges to accept locking screws 74 to be threaded into the other flange.

After the diseased section of bone has been removed, appliance 68 is temporarily fitted into place, and the angulation of the hinged strut assembly is adjusted until it duplicates the contour of the original jawbone. A locking means such as screws 74 are then inserted through holes 73 and threaded into the opposing flange to lock the flanges and struts of assembly 69 in the desired position.

Hinged strut assembly 69 is quite useful as it is often impossible to estimate the desired angulation of a prosthetic appliance until surgery is in progress. The hinged strut assembly can be quickly adjusted while temporarily installed, and then locked in place before permanent installation. The cylindrical form of strut 70 and the socket in the male coupler also assist in aligning and adjusting the position of the appliance, as rotation of the strut assembly with respect to the female coupler is permissible before the strut is locked in the socket.

Hinged strut assembly 69 is also useful in an appliance 78 which terminates at both ends in coupling assemblies 46 and this form of the invention is shown in FIG. 13. This style of the appliance is particularly useful to replace a removed bone section which formed an arcuate portion of the original bone. For example, appliance 78 is useful to reproduce the curvature of the chin in a mandible from which a major part of the body portion has been removed. It is also thought to be possible to build an entire artificial mandible using the various modular components of the invention described above.

The coupling assemblies described thus far are intended to secure together two members which are linearly aligned with respect to each other. However, this appliance is readily adapted for connection of angulated members, and this form of a male coupler 80 is shown in FIGS. 14 and 15. Coupler 80 includes a hollow tubular body portion 81 (or, alternatively, may be formed with an

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anchor plate as used in the male couplers shown in FIGS. 2-3) and a wall or boss 82 is formed across one end of the body portion. The boss has an outer face 83, the plane of which is oriented at an acute angle to the longitudinal axis of body portion 81. Extending from the central part of the outer face is a flange 84, and a tapered lock pin 85 is secured to the flange. The flange and lock pin are generally similar to those used in male couplers 22 and 50 described above, but the axis of the lock pin is oriented at about 45° to the longitudinal axis of the body portion. Other angulations can of course be selected depending upon the requirements of the particular surgical problem.

Male coupler 80 is shown in FIG. 15 as engaged with a female coupler 21. It will be clear from this illustration that bones or artificial members secured to the two couplers will extend away from each other at an angle corresponding to the angulation of the lock pin on the male coupler. This style of the appliance is of course useful in situations where the surgeon cannot estimate in advance what angulation will be required in the prosthetic appliance or bone graft.

The appliances are of course fabricated from materials compatible with the human body, and a variety of plastic and metal materials are available. The couplers are preferably integrally machined from stainless steel or integrally cast from a compatible alloy such as Vitallium. The struts can be metallic, or can be formed from plastic materials such as methyl-methacrylate polymers. Struts made of thermoplastic materials are preferred in some applications as they can be heated and bent or otherwise formed while surgery is in progress.

Although the invention has been described in terms of its application to surgery involving the lower jawbone, it is to be understood that these appliances are also useful in installing grafts or artificial elements in other parts of the body. The appliances are characterized by their flexibility and ease of use, and by the variety of configurations which can be assembled from the several modular components described herein.

What is claimed is:

1. A coupling assembly made of a material suitable for human-body implantation for securing a member to a bone, the bone having a lateral hole drilled therein adjacent one of its ends, the assembly comprising:

a female coupler having an anchor plate with a hole therethrough to accept a bone screw for securing the plate to the bone, and an elongated post secured at one end of the plate to extend substantially perpendicularly therefrom to fit in the lateral hole when the plate is secured to the bone, the post defining a lock socket extending longitudinally therein; and a male coupler having a body portion adapted to be secured to the member, and an elongated lock pin secured to the body portion and making a snug fit in the lock socket of the female coupler.

2. The coupling assembly defined in claim 1 in which the lock socket is tapered to have a large end and a small end, the pin having a decreasing cross section as it extends away from the plate in the post, and in which the lock pin is tapered to have a large end and a small end.

3. The coupling assembly defined in claim 2 in which the lock pin is shorter than the lock socket whereby the large end of the pin is disposed within the socket and spaced from the large end of the socket when the pin is fitted in the socket, and further comprising retaining means secured in the socket between the large end of the pin and the large end of the socket for locking the pin in the socket.

4. The coupling assembly defined in claim 3 in which the socket includes an annular groove adjacent its large end to provide an anchor for the retaining means.

5. The coupling assembly defined in claim 2 in which the body portion of the male coupler is formed as a

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second anchor plate, the second plate including a hole therethrough to accept a screw for securing the second plate to the member.

6. A prosthetic appliance made of a material suitable for human-body implantation for replacing a section of bone which has been removed between a first bone portion and a second bone portion, the first bone portion having a lateral hole drilled therein adjacent its end, comprising:

a female coupler having an anchor plate with a hole drilled therethrough to accept a bone screw for securing the plate to the first bone, and an elongated post secured at one end of the plate to extend laterally therefrom to make a snug fit in the lateral hole when the plate is secured to the first bone, the post defining a lock socket extending longitudinally therein; and

a male coupler having a body portion with a strut member extending therefrom, and an elongated lock pin secured to the body portion and making a snug fit in the lock socket of the female coupler.

7. A prosthetic appliance as defined in claim 6 in which the strut member has a distal end spaced from the body portion of the male coupler, and the distal end defines a knob-shaped prominence simulating a human condyle.

8. The prosthetic appliance as defined in claim 6 in which the body portion defines a strut socket, and in which the strut member is a cylindrical element secured in and extending from the socket.

9. The prosthetic appliance as defined in claim 6 in which the strut member has an end spaced from the body

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portion of the male coupler and defining a first flange, and further comprising a second strut member having an end defining a second flange, and pivotal attachment means for movably securing the flanges together whereby the angulation of the two strut members is adjustable.

10. The prosthetic appliance as defined in claim 9 and further comprising locking means engaged with the strut flanges for securing the struts at a selected angulation.

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U.S. Cl. X.R.

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United States Patent [19][11] **Patent Number:** **6,129,728****Schumacher et al.**[45] **Date of Patent:** **Oct. 10, 2000****[54] METHOD AND APPARATUS FOR
MANDIBULAR OSTEOSYNTHESIS****[75] Inventors:** Brian S. Schumacher; Kevin T. Stone;
Jeffrey A. Duncan, all of Jacksonville,
Fla.**[73] Assignee:** Walter Lorenz Surgical, Inc.,
Jacksonville, Fla.**[21] Appl. No.:** 09/025,140**[22] Filed:** Feb. 18, 1998**[51] Int. Cl.⁷** **A61B 17/56****[52] U.S. Cl.** **606/71; 606/69; 606/73;**
606/104**[58] Field of Search** **606/69, 70, 71,**
606/73**[56] References Cited****U.S. PATENT DOCUMENTS**

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Primary Examiner—Michael Buiz*Assistant Examiner*—David O. Reip*Attorney, Agent, or Firm*—Harness, Dickey & Pierce, P.L.C.**[57] ABSTRACT**

A system for mandibular reconstruction generally includes an elongated locking plate having a plurality of internally threaded apertures and a plurality of fasteners. Each fastener includes a main body portion having an upper threaded shaft and a lower threaded shaft. The lower threaded shaft is adapted to engage the mandible. Each fastener further includes a removable head portion internally threaded for engaging the upper shaft portion and externally threaded for engaging a selected one of the internally threaded apertures of the locking plate. In the preferred embodiment, the thread leads of the head portion and lower shaft of the main body portion are identical. A method of mandibular osteosynthesis utilizes the system of osteosynthesis and generally comprises the steps of temporarily securing the elongated locking plate to the mandible with at least one fastener by engaging the threads of the lower portion with the mandible and threadably engaging the head with the locking plate, unthreading the head portion from the main body of the fastener to thereby allow displacement of the locking plate from the mandible without removing the fasteners from the mandible, performing a surgical procedure (e.g., removal of a cancerous growth), and re-securing the elongated plate to the fastener with the removable head portion.

23 Claims, 3 Drawing Sheets